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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,558	09/22/2000	Frances Yen	70.US2.REG	5403

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	12

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/668,558	YEN ET AL.	
	Examiner	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 5, drawn to leptin polypeptides, classified in class 530, subclass 350.

II. Claims 2-4, drawn to polynucleotides encoding leptin polypeptides, classified in class 536, subclass 23.5.

III. Claims 6 and 7, drawn to a method of treatment comprising administration of leptin polypeptides, classified in class 514, subclass 2.

IV. Claim 8, drawn to a method of designing mimetics of a leptin fragment that modulates an activity of lipolysis stimulated receptor (LSR), classified in class 702, subclass 22, for example.

V. Claims 9 and 12, drawn to chimeric oligonucleotides, classified in class 536, subclass 23.5.

VI. Claims 10, 11, 13 and 19, drawn to a method of gene therapy comprising administration of a chimeric oligonucleotide, classified in class 514, subclass 44.

VII. Claim 14, drawn to zinc finger proteins, classified in class 530, subclass 350.

VIII. Claims 15, 16, 21 and 24, drawn to polynucleotides encoding zinc finger proteins, classified in class 536, subclass 23.5.

IX. Claim 17, drawn to a method of gene therapy therapy comprising administration of polynucleotides encoding zinc finger proteins, classified in class 514, subclass 44.

X. Claim 18, drawn to a transgenic animal, classified in class 800, subclass 3.

XI. Claims 22, 23 and 25-28, drawn to a method of screening for LSR modulating compounds in cells transformed with polynucleotides encoding zinc finger proteins, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the leptin polypeptides of invention I are structurally and functionally different types of proteins from the zinc finger proteins of invention VIII. Similarly, inventions II and VIII, drawn to polynucleotides encoding the leptin and zinc finger polypeptides, are also unrelated, because they have different nucleotide sequences and have different functions, and encode different types of proteins.

Each of Inventions I and II and inventions VII and VIII are related in that the polynucleotides of inventions II and VIII encode the polypeptides of inventions I and VII, and so can be used to make the polypeptides, but they are structurally and functionally different chemical compounds.

Inventions I and each of inventions III, IV and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the leptin polypeptides can be used in

a method of therapy as in invention III, or in a method of designing mimetics of a leptin fragment that is invention III, or in a method of screening for LSR modulating activity that is invention XI, which are materially different methods having different method steps, starting materials and goals. Similarly, invention II and each of inventions III, IV and XI are related as product of making a product and process of using that product, since the polynucleotides of invention II encodes the polypeptides of invention I and can be used to recombinantly produce the polypeptides.

Invention I is unrelated to each of inventions V, VI, IX and X. In the instant case the leptin polypeptides are structurally and functionally distinct from the chimeric oligonucleotides of invention V and are not used or defined in the methods of gene therapy of invention VI and IX or the transgenic animal of invention X. Similarly, invention II is unrelated to each of inventions V, VI, IX and X, since the polynucleotides of invention II encodes the polypeptides of invention and can be used to recombinantly produce the polypeptides.

Inventions VII and XI process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the zinc finger proteins of invention VII are used in the method of screening of invention XI, but the zinc finger proteins can also be used in a method of generating antibodies, which is a materially different method.

Invention VII is unrelated to each of inventions III-VI, IX and X. In the instant case the zinc finger polypeptides are not used or defined in the methods or are structurally and functionally different compounds from the other products.

Invention VIII is related to each of inventions IX, X and XI as product and process of using or making. In the instant case the polynucleotides encoding the zinc finger proteins of invention VIII can be used in the method of gene therapy of invention IX, or to make the transgenic mammal of invention X, or in the method of screening for LSR modulating activity of invention XI, all of which are materially different methods having different starting materials, method steps and goals.

Invention VIII is unrelated to each of inventions III-VI. In the instant case the polynucleotides encoding the zinc finger proteins are not used or defined in the methods, and are structurally and functionally distinct compounds from the chimeric oligonucleotides.

Invention X is unrelated to each of inventions III-VI, IX and XI. In the instant case, the transgenic animal is not used or defined in the methods, and is a structurally and functionally different product from the chimeric oligonucleotides.

Invention V is related to invention VI in that the chimeric oligonucleotide of invention V is used in the method of gene therapy, but the oligonucleotide can also be used in a method of hybridization, which is a materially different method.

Invention V is unrelated to each of inventions III, IV and IX-X. In the instant case the chimeric oligonucleotide of invention V is not used or defined in the methods.

Each of the remaining methods (III, IV, VI, IX, and XI) are unrelated to each other. The different methods have different starting materials, have different method steps and goals.

Further Restriction Within Groups I, III and XI

3. Applicants' claims are drawn to numerous patentably distinct leptin polypeptide sequences. If any of groups I, III and XI is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct polypeptide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a polypeptide, selected from the group consisting of: (i.e. elect one from the following Markush group):a polypeptide having an amino acid sequence selected SEQ ID NOS: 28-39. Applicants should note that in some cases multiple claims encompass one of the patentably distinct inventions set forth herein.

Further Restriction Within Group II

4. Applicants' claims are drawn to numerous patentably distinct polynucleotides encoding leptin polypeptide sequences. If group II is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct polynucoeotides encoding polypeptide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a polypeptide, selected from the group consisting of:

(i.e. elect one from the following Markush group):a polynucleotide encoding a polypeptide having an amino acid sequence selected SEQ ID NOS: 28-39. Applicants should note that in some cases multiple claims encompass one of the patentably distinct inventions set forth herein.

Further Restriction Within Groups V and VI

5. Applicants' claims are drawn to numerous patentably distinct chimeric oligonucleotide. If groups V or VI is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct chimeric oligonucleotide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of an oligonucleotide, selected from the group consisting of: (i.e. elect one from the following Markush group):an oligonucleotide comprising at least 9 contiguous nucleotides from a sequence selected from the group consisting of SEQ ID NOS: 2, 4, 6, 8, 10, 12, 14, 15 and 16. Applicants should note that in some cases multiple claims encompass one of the patentably distinct inventions set forth herein.

Further Restriction Within Group VIII

6. Applicants' claims are drawn to numerous patentably distinct LSR polypeptides. If group VIII is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct LSR polypeptide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a polypeptide, selected from the group consisting of: (i.e. elect one from the following Markush group):a polypeptide comprising a sequence selected from the group consisting of SEQ ID NOS: 3, 5, 7, 9, 11, 13, 17, 18 and 19. Applicants should note that in some cases multiple claims encompass one of the patentably distinct inventions set forth herein.

Applicant is advised that this is not a species election.

Although the classifications for these various nucleic acids and polypeptides are overlapping, for instance 536/23.1 or 530/350, each represents a patentably distinct product with distinct physical and functional characteristics. Further, the search for more than one product would be burdensome, because, in the case of some nucleic acid sequences, they are claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of the nucleic acid as well as a 'reverse translation' search of the corresponding region of the protein, such that each individual sequence requires two sequence searches which are not required for any of the other sequences, and by virtue of comprising only a small portion of a disclosed nucleic acid or polypeptide, which requires a separate "word search" of the nucleic acid and protein databases. Accordingly, restriction is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and the need for non-coextensive literature search and/or separate sequence database searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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